## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

HORIZON PHARMA, INC. and HORIZON PHARMA USA, INC.,

Plaintiffs,

C.A. No. 12-cv-00393-LPS

v.

PAR PHARMACEUTICAL COMPANIES, INC. and PAR PHARMACEUTICAL, INC.,

Defendants.

# PLAINTIFFS HORIZON PHARMA, INC. AND HORIZON PHARMA USA, INC.'S ANSWER TO COUNTERCLAIM OF PAR PHARMACEUTICAL COMPANIES, INC. AND PAR PHARMACEUTICAL, INC.

Plaintiffs Horizon Pharma, Inc. and Horizon Pharma USA, Inc. (collectively, "Horizon") by their undersigned attorneys, respond as follows to the Counterclaim filed by Defendants Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (collectively, "Par"). Answers to Par's specific allegations are contained below in numbered paragraphs that correspond to the numbered paragraphs of Par's Counterclaim. Horizon denies any allegation not expressly admitted in this Answer.

#### THE PARTIES

1. Horizon lacks sufficient knowledge or information to form a belief as to the

truth of the allegations set forth in Paragraph 1 of Par's Counterclaim and, therefore, denies them.

- 2. Horizon lacks sufficient knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 2 of Par's Counterclaim and, therefore, denies them.
  - 3. Admitted.
  - 4. Admitted.

#### **NATURE OF THE ACTION**

5. Horizon denies that U.S. Patent No. 8,067,033 is invalid and not infringed by Par. Horizon admits that Par seeks a declaratory judgment that U.S. Patent No. 8,067,033 is invalid and not infringed but denies that Par is entitled to such judgment.

#### **JURISDICTION**

- 6. Admitted.
- 7. Horizon does not contest personal jurisdiction relevant to the counterclaim asserted herein.

#### **VENUE**

8. Horizon does not contest venue relevant to the counterclaim asserted herein.

#### **BACKGROUND**

- 9. Admitted.
- 10. Admitted.

- 11. Admitted.
- 12. Admitted that Par purports to have filed ANDA No. 203658 ("Par's ANDA"), which allegedly seeks FDA approval to market generic famotidine and ibuprofen tablets for oral administration (26.6 mg; 800 mg), based on Horizon's Duexis® NDA. It is further admitted that Par asserts that, as part of Par's ANDA, Par Pharmaceutical, Inc. included a Paragraph IV certification pursuant to 21 U.S.C. §§ 355(j)(2)(A)(vii)(IV), asserting that the '033 patent will not be infringed by the products described in Par's ANDA and/or the '033 patent is invalid and/or unenforceable. Horizon lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations set forth in Paragraph 12 of Par's Counterclaim and, therefore, denies them.
- 13. Admitted that Horizon received on or about February 15, 2012, a letter which Par alleges constitutes notice of its alleged certification pursuant to 21 U.S. C. § 355(j)(2)(B)(ii). It is further admitted that the letter included what Par purports to be a detailed statement of the factual and legal bases for the Paragraph IV certification and an offer of confidential access to ANDA No. 203658. Horizon denies any remaining allegations set forth in Paragraph 13 of Par's Counterclaim.
  - 14. Admitted.
- 15. Admitted that Horizon filed the Complaint in the present action prior to obtaining or reviewing a copy of Par's ANDA. Horizon denies any remaining allegations set forth in Paragraph 15 of Par's Counterclaim.
  - 16. Denied.

#### **COUNT ONE**

### (Declaratory Judgment regarding U.S. Patent No. 8,067,033)

- 17. Horizon reasserts it responses to Paragraphs 1-16 of Par's Counterclaim as if fully set forth herein.
- 18. Paragraph 18 sets forth legal conclusions to which no answer is required. To the extent an answer to any factual allegations set forth therein is required, Horizon denies them.
- 19. Paragraph 19 sets forth legal conclusions to which no answer is required. To the extent an answer to any factual allegations set forth therein is required, Horizon denies them.
- 20. Paragraph 20 sets forth legal conclusions to which no answer is required. To the extent an answer to any factual allegations set forth therein is required, Horizon denies them.
- 21. Paragraph 21 sets forth legal conclusions to which no answer is required. To the extent an answer is required, Horizon admits that an actual and justiciable controversy exists between Horizon and Par regarding the infringement and validity of the '033 patent.

  Except as stated herein, Horizon denies the allegations of Paragraph 21 of Par's Counterclaim.
- 22. Paragraph 22 sets forth legal conclusions to which no answer is required. To the extent an answer to any factual allegations set forth therein is required, Horizon denies them.

#### PRAYER FOR RELIEF

The lettered paragraphs following the heading "Prayer For Relief" are requests for relief to which no response is required. To the extent any of these lettered Paragraphs are deemed to contain factual allegations, Horizon denies them, and further denies that Par is entitled to any of the relief requested therein or to any other relief whatsoever.

#### **DEFENSES**

Par's counterclaim fails to state a claim upon which relief may be granted.

#### **RELIEF SOUGHT**

WHEREFORE, Horizon respectfully requests the following relief:

- A. Entry of judgment in favor of Horizon and against Par with respect to Par's Counterclaim, and an award of the relief sought in Horizon's Complaint;
  - B. Dismissal of Par's Counterclaim with prejudice;
  - C. An award to Horizon of its attorneys fees, costs and expenses; and
  - D. Such other relief as the Court deems equitable and just.

#### Respectfully submitted,

Date: May 17, 2012

/s/John C. Phillips, Jr.

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